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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/596,948

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Chad J. Carter

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EXAMINER

NAGPAUL, JYOTI

ART UNIT

PAPER NUMBER

1773

NOTIFICATION DATE

DELIVERY MODE

12/08/2010

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/596,948	<b>Applicant(s)</b> CARTER ET AL.	
	<b>Examiner</b> JYOTI NAGPAUL	<b>Art Unit</b> 1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 30 September 2010.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-16, 18, 20-31 and 33-40 is/are pending in the application.
- 4a) Of the above claim(s) 21-26, 33, 34 and 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-16, 18, 20, 27-31 and 35-39 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

Amendment filed on September 30, 2010 is acknowledged. Claims 1-6, 8-16, 18, 20, 27-31 and 35-39 are pending.

#### ***Response to Amendment***

Rejection of Claims 1-9 and 11-17 as being anticipated by Buechler (US 6156270) has been maintained in light of applicants' amendments.

Rejection of Claim 10 as being unpatentable over Buechler has been maintained in light of applicants' amendments.

Rejection of Claims 18-20 as being unpatentable over Buechler in view of Wiegner (US 4103772) has been maintained in light of applicants' amendments.

Rejection of Claims 27-32 and 35-39 as being anticipated by Wiegner (US 4103722) has been maintained in light of applicants' amendments.

#### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "input port" as recited in claim 35 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

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is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. **Claims 1-6, 8-10 and 12-16** are rejected under 35 U.S.C. 102(b) as being anticipated by Buechler (US 6156270).

Buechler teaches a detection cartridge comprising a housing (9) comprising an interior volume, a sensor operably attached to the housing, refer to Col. 7, lines 4-7, the sensor comprising a detection surface. It is inherent that that aousto-mechanical sensor has a detection surface and it must be attached to the device of Buechler. Buechler further teaches a detection chamber (6) located within the interior volume of the housing

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(9). The detection chamber (6) comprises a volume defined by the detection surface and an opposing surface spaced apart from and facing the detection surface, wherein the opposing surface comprises a flow front control feature (grooves). (Refer to Figure 1) Buechler further teaches a waste chamber (7) located within the interior volume of the housing (9), the waste chamber in fluid communication with the detection chamber (6). (Refer to Figure 1) According to Col. 7, Lines 4-7, the detection surface comprises an acousto-mechanical waveguide and a surface acoustic wave acousto-mechanical sensor. According to Figures 1-1A, the flow front control feature (grooves) comprises discrete structures protruding from and separated by a land area on the opposing surface of the detection chamber and the flow front control feature (grooves) comprises one or more channels in the opposing surface of detection chamber (6). According to Figure 1, at least one channel of the one or more channels is oriented generally perpendicular to a longitudinal axis defined within the detection chamber (6) between an input end and an output end of the waste chamber (7). The flow front control feature (groove) comprises one or more regions of hydrophobic material occupying a portion of the opposing surface and one or more regions of hydrophilic material occupying a portion of the opposing surface. (Refer to Col. 5, Lines 40-50) Buechler further teaches at least one pair of successive bands of hydrophobic material and hydrophilic material wherein each pair of successive bands extends across a width of the detection chamber (6). (Refer to Col. 5, Lines 40-50 and Figure 1) Buechler further teaches the cartridge further comprises capillary structure; refer to figure 2, located between the detection chamber (6) and the waste chamber (7). Buechler further teaches a vent, refer to col. 4,

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line 37, that, when open, places the interior volume of the housing in fluid communication with ambient atmosphere around the cartridge. Buechler further teaches the vent comprises a closure element (64). (Refer to Col. 36, Lines 1-6) Buechler further teaches a staging chamber (1) within the interior volume of the cartridge housing and is located upstream from the detection chamber (6) and the module ports open (the opening of (1) in figure 1a) into the staging chamber (1).

***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

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not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. **Claim 11** is rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler.

Refer above for the teachings of Buechler.

Buechler fails to explicitly teach absorbent material located within the waste chamber (7). Buechler does teach filter elements in the sample addition zone (1) to filter particulates from the sample. (Refer to Col. 8, Lines 50-55)

It would have been obvious to one having ordinary skill in the art to provide the waste chamber of Buechler with an absorbent material in order to filter particulates from the sample.

### ***Claim Rejections - 35 USC § 103***

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

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4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. **Claims 18 and 20** are rejected under 35 U.S.C. 103(a) as being unpatentable over Buechler in view of Wiegner (US 4103772).

Refer above for the teachings of Buechler.

Buechler fails to teach one or more sealed modules, wherein each module of the one or more sealed modules comprises an exit port attached to the cartridge housing through one or more module ports that open into the interior volume of the cartridge housing, and wherein each module further comprises: a module housing comprising an exit port and a sealed interior volume, an exit seal located over the exit port of the module; and a plunger located within the interior volume of the module housing, wherein the plunger is movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port; wherein movement of the plunger towards the exit port opens the exit seal such that material from the interior volume of the module housing exits through the exit port into the interior volume of the cartridge housing.

Wiegner teaches disposable container comprising a module housing comprising an exit port and a sealed interior volume, an exit seal located over the exit port of the module; and a plunger (6) located within the interior volume of the module housing (2), wherein the plunger is movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which the plunger is proximate the exit port; wherein movement of the plunger towards the exit port opens the exit seal such that



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material from the interior volume of the module housing exits through the exit port into the interior volume of the cartridge housing. (Refer to Figure 1)

It would have been obvious to one having ordinary skill in the art to provide the device of Buechler with the container of Wiegner in order to ensure no contamination of sample when introducing the sample to the sample addition zone of Buechler.

***Claim Rejections - 35 USC § 102***

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12. **Claims 27-31 and 35-39** are rejected under 35 U.S.C. 102(b) as being anticipated by Wiegner (US 4103722).

Wiegner teaches a housing (2) comprising an exit port and a sealed interior volume, refer to figure 1, an exit seal located over the exit port (4), a first chamber (11) located within the interior volume of the housing (2), the first chamber comprising a liquid located therein, refer to Figure 1, a second chamber (1) located within the interior volume of the housing (2), the second chamber comprising a reagent located therein, refer to Figure 1, an inter-chamber seal (7) isolating the second chamber from the first chamber within the housing (2) and a plunger (6), wherein the first chamber, the inter-chamber seal, the second chamber, and the exit seal are located between the plunger and the exit port. (Refer to Figure 1) The plunger (6) is movable from a loaded position in which the plunger is distal from the exit port to an unloaded position in which

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the plunger is proximate the exit port. The movement of the plunger (6) towards the exit port (4) opens the inter-chamber seal (7) such that the liquid in the first chamber contacts the reagent in the second chamber and the unloaded position opens the exit seal such that the liquid and the reagent from the interior volume of the housing exit through the exit port (4). The plunger (6) comprises a tip, refer to Figure 1,, wherein the tip faces the inter-chamber seal and wherein the tip pierces the inter-chamber seal to open the inter-chamber seal. Applicants recite “wherein the liquid in the first chamber comprises a water and the reagent in the second chamber comprises a hydrolyzable material.” Applicants are claiming an apparatus statutory class of invention and it is fundamental that an apparatus claim defines the **structure** of the invention and **not** how the structure is used in a process or what materials the structure houses in carrying out the process. Therefore, the apparatus of Wiegner is capable of having a first chamber with water and the second chamber with reagent comprising a hydrolyzable material.

### ***Response to Arguments***

13. Applicant's arguments filed September 30, 2010 have been fully considered but they are not persuasive. With regards to claim 1, Applicants argue that Buechler does not disclose that the opposing surface may be both hydrophobic and hydrophilic. Examiner respectfully disagrees. It is the examiner's position that Buechler teaches, in Col. 17, Line 24-30, that the hydrophobic surfaces opposing the diagnostic element can have tendency to become hydrophilic as the reaction mixture progresses through the diagnostic element. Therefore, in this teaching, one of ordinary skill in the art can concur that some portions of the opposing surface can be hydrophobic and hydrophilic

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depending on the progression of the reaction mixture. With regards to claim 27, applicants argue that Wiegner does not teach the liquid in the first chamber comprises a water and the reagent in the second chamber comprises a hydrolyzable material. Refer to rejection above. With regards to claim 35, applicants argue that Wiegner does not disclose a input port. Examiner respectfully disagrees. Wiegner teaches it in figure 1. With respect to claim 18, applicants argue that Buechler does not teach a staging chamber within the interior volume of the cartridge housing and is located upstream from the detection chamber and the module ports open (the opening of (1) in figure 1a) into the staging chamber (1). Examiner respectfully disagrees. Refer to rejection above.

### ***Conclusion***

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JYOTI NAGPAUL whose telephone number is (571)272-1273. The examiner can normally be reached on Monday thru Friday (10:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jyoti Nagpaul/  
Primary Examiner, Art Unit 1773